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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,868	07/17/2000	Thomas J. Shaw	75329 77432	8293

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/617,868

Applicant(s)

SHAW, THOMAS J.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 58-77, 79-86, 88-94, 107 and 108 is/are allowed.
- 6) ☒ Claim(s) 29-34, 36-42, 44-50, 52, 54, 55, 96, 102-106, 109-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 29-34,36-42,44-50,52,54,55,58-77,79-86,88-94,96,102-121.

DETAILED ACTION

This action is in response to applicant's amendments submitted 29 March 2007

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsao (US 5,084,018).

Regarding claim 96, Tsao teaches a syringe assembly having a hollow body with an inside wall (19), a retraction assembly with a spring (38), a needle holder (34) and a retainer member (20), a plunger (50) with a tip (56) having a smaller tip opening (54), a seal (58), and a rigid stop surface (26).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 29-34, 36-42, 44-50, 52, 54-55, 102-106, 109-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsao (US 5,084,018) in view of Mercado (US 5,304,138).

Regarding claims 29,37,45,110,111,113-120 Tsao teaches a syringe assembly having a retractable needle and designed for one-time use, comprising: a hollow syringe body comprising a barrel (12) having a front end portion containing a retraction mechanism/biasing element (generally 38) having a retractable needle (30), a needle holder having an inner head/needle holder (34) (19 is also considered a part of the needle holding portion since it holds head 34 in place) and a continuous retaining member (20) configured for operation by forward movement of a plunger (50), and a back end portion having an opening (above 11); the continuous retaining member surrounding the inner head of the needle holder and having a surface mating (26 and 28) with a facing surface of the hollow syringe body, thereby making a seal for a variable fluid chamber in the barrel; a plunger having a front end portion (54) comprising a head (56), an outer wall surface on the plunger front end portion having a plunger seal (58) element fixed on the outer wall surface, and a back end portion with an end cap (57) having an outer periphery; the plunger being reciprocally mounted in said barrel with the plunger seal element in sliding sealed contact with the barrel; and the retraction mechanism being released for retraction of the retractable needle when the plunger is moved forward to release the continuous retaining member, without moving the plunger seal element longitudinally along the outer wall surface by contact between the plunger seal element and the continuous retaining member, the outer periphery of the plunger end cap being receivable into the opening in the back end portion of the hollow syringe body upon retraction. See the progression from Fig 1 to Fig 4. Forward motion of the needle prior to and during retraction is limited by barrier 19.

Tsao does not teach a radially extending member having a front side and a back side with a collar extending rearwardly behind the back side of the radially extending member.

Mercado teaches a single use syringe with a radially extending member (20) and a collar (18) extending rearwardly of the back surface of the radially extending member, with the barrel having a different diameter (Fig 1)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the rearwardly extending collar of Mercado with the needle retraction mechanism of Tsao in order to prevent the plunger from being withdrawn and the syringe from being reused (Mercado Col 1 lines 40-53).

Regarding claims 30, 39, and 47 a structure (walls of the needle extender 19 which prevent 34 from moving forward) mounted in the front end portion of the barrel prevents forward motion of the retractable needle during retraction of the needle to prevent pain when the needle is retracted from a patient.

Regarding claims 31,41,42, and 49 the plunger carries a tip (the walls of the plunger approximately indicated by 54) which protrudes to contact the continuous

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retaining member and release the retractable needle when retraction is initiated by pushing on the plunger. See Fig 3 especially, which shows the walls pushing on the retainer 20 to allow the cork 56 to be displaced and inner head 34 to withdraw into the syringe barrel under the force of spring 38.

Regarding claims 32,38, and 46, the continuous retaining member is a separable part of the retraction mechanism which acts as a fluid seal for a variable chamber in the barrel behind the separable part. See Fig 1

Regarding claims 33 and 48 the continuous retaining member is separable from the inner head of the needle holder when retraction is initiated by pushing on the plunger. See Fig 3

Regarding claims 34, 40, 50, and 55 the continuous retaining member is separated from the inner head of the needle holder by means of force applied by said tip to said continuous retaining member when retraction is initiated by pushing on said plunger. See Fig 3

Regarding claims 36, 44, and 52, the outer periphery of the plunger end cap is lodged in close confinement with the back end portion of the collar by pressing the end cap to cause retraction, whereby the plunger cannot be grasped after retraction. See Fig 4 and note the interaction between limiting flanges 11 and 14.

Regarding claim 105, the needle holding portion 19 extends forwardly of the body 12

As to claim 106, stops 26; claim 109, Fig 1; claims 112 and 120, the retraction cavity is vented by the open end of the syringe after retraction (Fig 4)

Allowable Subject Matter

3. Claims 58-77, 79-86, 88-94, 107, 108 are allowed.

Response to Arguments

4. Applicant's arguments filed 23 February 2007 and 29 March 2007 have been fully considered but they are not persuasive.

Regarding Tsao, applicant has argued:

Spring 38 is not a retraction mechanism. This is not persuasive because spring, specifically identified with respect to figures 1-4, not 5, is used to retract the needle. All of applicant's arguments regarding the embodiments of Tsao shown in figures 5 and 6 are not relevant because the office action specifically refers to Figures 1-4 as the illustrating embodiment.

The outer periphery of the end cap is any proximal portion of the plunger, and is shown within the barrel following retraction in Figure 4.

The "needle holding portion" is not given a special definition requiring it to touch or be in contact with the needle. Rather, the "needle holding portion" is any portion which is used to guide or stabilize the needle in use. This includes extension 19, which may also be considered a part of the inner wall of the syringe since it is integral with the

barrel, especially as interpreted by the examiner with regards to the part of 19 which extends inside the barrel and guides the retraction spring 38.

Regarding applicant's arguments about the functionality of the Tsao syringe, without providing specific evidence that the syringe of Tsao is unworkable, the examiner does not believe that this argument overcomes the disclosure of the structural features the applicant is claiming as illustrated in the Figures 1-4 of Tsao.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elizabeth R. MacNeill
3/29/06

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons